UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,286	12/21/2001	Michael J. Robarge	9516-048-999	6358

20583 7590 09/16/2004

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,286	ROBARGE ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-39,41-47,49-52 and 57-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-39,41-47,49-52 and 57-100* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a RCE of SN 10/032,286. Claims 40, 48, 53-56 have been canceled. Claims 71-100 have been added. In view of the newly added claims with newly available prior art, a restriction is hereby necessitated.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-39, 71-83, 97-100, 41-47, 94, drawn to compounds, stereoisosmers, racemates and salts of formula of claim 1, classified in class 546, subclass various, depending on species election. Proper classification can only be made upon election of a particular species.

II. Claims 47 and 64, drawn to method of modulating TNF-α, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of compound for particular end pathology is also required.

III. Claims 50 and 65, drawn to method of modulating IL-1β, classified in class 514, subclass various depending on species election. If this group is elected, a further election of a single disclosed species of compound for particular end pathology is also required.

IV. Claims 51 and 66, drawn to method of modulating IL-10, classified in class 514, subclass various depending on species election. If this group is elected, a further election of a single disclosed species of compound for a particular end pathology is also required.

V. Claims 52 and 67, drawn to method of modulating production or proliferation of T-cells, classified in class 514, subclass various depending on species election. If this group is elected, a further election of a single disclosed species of compound for a particular end pathology is also required.

VI. Claims 57 and 85-88, drawn to method of treating cancer, classified in class 514, subclass various depending on species election. If this group is elected, a further

election of a single disclosed species of compound for a particular cancer is also required.

VII. Claim 58 drawn to method of treating cancer with multiple drugs, classified in class 514, subclass various depending on species election. If this group is elected, a further election of a single disclosed combination of active compounds and a particular cancer for the method is also required. Further restriction may be required.

VIII. Claim 59, drawn to method of treating cancer with combination of drug and vaccine, classified in class 514, subclass various depending on species election. If this group is elected, a further election of a single disclosed species of compound being combined with a single disclosed vaccine for a particular cancer is also required.

IX. Claims 60-62, drawn to method of treating inflammatory disease classified in class 514, subclass various depending on species election. If this group is elected, a further election of a single disclosed species of compound for a particular inflammatory disease is also required.

X. Claim 63, drawn to method of treating heart disease, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed compound for treating heart disease is also required.

XI. Claims 68-70, drawn to method of modulating cytokine, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of compound for a particular end pathology is also required.

XII. Claims 91-92, drawn to solvates and method of using, classified in class 546, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of solvate for treating a particular disease/pathology is also required.

XIII. Claims 93-94, drawn to hydrates and method of using, classified in class 546, subclass various, depending on species election. If this group is elected, a further

election of a single disclosed species of hydrate for treating a particular disease/pathology is also required.

XIV. Claims 95-96, drawn to clathrates and method of using, classified in class 546, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of clathrates for treating a particular disease/pathology is also required.

The inventions are distinct, each from the other because:

Groups I and XII-XIV inventions are independent and distinct because hydrates, solvates and clathrates are *patentably distinct* products from the compounds i.e. magnesium sulfate anhydrous is a different "product" from magnesium sulfate.$7H_2O$. Not only hydrates are considered separate compounds from none hydrated compounds, the number of water content also determines the identify of the product, i.e. monohydrates, dehydrates etc. The chemical nature i.e. element content, bonding arrangements and chemical properties, among the different *products* are different and the search for compound per se is not co-extensive to the hydrates, solvates or clathrates since they are considered "independent and distinct entities" by chemists.

Inventions I, XII-XIV and II-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating prostate cancer can be practiced by a material different product i.e. thalidomide (see Joseph et al.).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C.§ 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. *Applicants are reminded of propriety of process of use claims in consideration of the "reach-trough" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease.* **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Sept. 10, 2004

Celia Chang
Primary Examiner
Art Unit 1625